

# **Scientific Documentation**

D1097, Diethyl Phthalate, NF

Not appropriate for regulatory submission. Please visit <a href="www.spectrumchemical.com">www.spectrumchemical.com</a> or contact Tech Services for the most up-to-date information contained in this information package.

### **Spectrum Chemical Mfg Corp**

769 Jersey Avenue New Brunswick, NJ 08901 Phone 732.214.1300



Dear Customer,

Thank you for your interest in Spectrum's quality products and services.

Spectrum has been proudly serving the scientific community for over 45 years. It is our mission to manufacture and distribute fine chemicals and laboratory products with Quality and delivery you can count on every time.

To accomplish our mission, Spectrum utilizes our sourcing leverage and supplier qualification expertise in offering one of the industry's most comprehensive line of fine chemical products under one brand, in packaging configurations designed to meet your research and production requirements. Our product grades include: USP, NF, BP, EP, JP, FCC, ACS, KSA, Reagent grade, as well as DEA controlled substances. We operate facilities in the United States on the East Coast, West Coast, as well as in Shanghai, China in order to provide the best logistical support for our customers.

At Spectrum, Quality is priority number one. Suppliers with the best qualifications are preferred and we employ full-functioning in-house analytical laboratories at each of our facilities. Our facilities and systems are USFDA registered and ISO certified. We frequently host customer audits and cherish opportunities for improvements. Quality is engrained into our culture. Quality is priority number one.

In the following pages, we have designed and prepared documented scientific information to aid you in your initial qualification or your continual use of our products. Please do not hesitate to contact us if further information or the most up-to-date documentation is desired from any of the covered areas.

We appreciate your business and we look forward to hearing from you.

Sincerely,

Alan Wang, MSQA, ASQ CQA Director of Technical Services techservices@spectrumchemical.com

31.May.2017

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## Specification for Diethyl Phthalate, NF (D1097)

Item Number	<u>D1097</u>
Item	Diethyl Phthalate, NF
CAS Number	84-66-2
Molecular Formula	$C_{12}H_{14}O_4$
Molecular Weight	222.24
MDL Number	
Synonyms	1,2-Benzenedicarboxylic Acid, Diethyl Ester; Ethyl Phthalate

Test	Specifi	ication
	Min	Max
ASSAY (ANHYDROUS BASIS)	98.0	102.0 %
SPECIFIC GRAVITY @ 20°C	1.118	1.122
REFRACTIVE INDEX @ 20°C	1.500	1.505
WATER DETERMINATION		0.2 %
ACIDITY		TO PASS TEST
RESIDUE ON IGNITION		0.02 %
IDENTIFICATION		TO PASS TEST
EXPIRATION DATE		
DATE OF MANUFACTURE		
APPEARANCE		
RESIDUAL SOLVENTS		TO PASS TEST

#### Spectrum Chemical Mfg Corp

Corporate Headquarters:West Coast Facility:769 Jersey Ave.14422 S. San Pedro St.New Brunswick, NJ 08901Gardena, CA 90248

732.214.1300 310.516.8000





## **SAFETY DATA SHEET**

Preparation Date: No data available Revision Date: 03/21/2015 Revision Number: G1

**Product identifier** 

Product code: D1097

Product Name: DIETHYL PHTHALATE, NF

Other means of identification

**Synonyms:** 1,2-Benzenedicarboxylic acid, diethyl ester

Anozol DEP

DPX-F5384

Diethyl 1,2-benzenedicarboxylate

Diethyl o-phthalate Diethyl phthalate

Diethyl phthalate (ACGIH)

Diethylester Kyseliny ftalove (Czech)

Ethyl phthalate NCI-C60048 Neantine Palatinol A Phthalol

Phthalsaeurediaehtylester

Placidol E

RCRA waste number U088

Solvanol Unimoll DA

o-Benzenedicarboxylic acid diethyl ester

Tumorigen Mutagen

Reproductive Effector Human Data

Primary Irritant

CAS #: 84-66-2
RTECS # TI1050000
CI#: Not available

Recommended use of the chemical and restrictions on use

**Recommended use:**Uses advised against
Solvent for cellulose acetate.
No information available

**Supplier:** Spectrum Chemicals and Laboratory Products, Inc.

14422 South San Pedro St. Gardena. CA 90248

(310) 516-8000

Order Online At: https://www.spectrumchemical.com

Emergency telephone numberChemtrec 1-800-424-9300Contact Person:Martin LaBenz (West Coast)Contact Person:Ibad Tirmiz (East Coast)

Product code: D1097 Product name: DIETHYL PHTHALATE, 1 / 13

#### 2. HAZARDS IDENTIFICATION

#### Classification

This chemical is considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

Serious eye damage/eye irritation	Category 2B
Specific target organ toxicity (single exposure)	Category 3

#### Label elements

#### Warning

#### Hazard statements

Causes mild skin irritation

Causes eye irritation

May cause respiratory irritation. May cause drowsiness or dizziness



#### Hazards not otherwise classified (HNOC)

Not Applicable

#### Other hazards

May be harmful if inhaled
Harmful to aquatic life with long lasting effects
Harmful to aquatic life

#### **Precautionary Statements - Prevention**

Wash face, hands and any exposed skin thoroughly after handling Avoid breathing dust/fume/gas/mist/vapors/spray Use only outdoors or in a well-ventilated area

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.

IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing. Call a POISON CENTER or doctor/physician if you feel unwell.

#### **Precautionary Statements - Storage**

Store in a well-ventilated place. Keep container tightly closed Store locked up

#### **Precautionary Statements - Disposal**

Dispose of contents/container to an approved waste disposal plant

#### 3. COMPOSITION/INFORMATION ON INGREDIENTS

Components	CAS-No.	Weight %	Trade Secret
Diethyl Phthalate	84-66-2	100	*
84-66-2			

Product code: D1097 Product name: DIETHYL PHTHALATE, 2 / 13

#### 4. FIRST AID MEASURES

First aid measures

General Advice: Poison information centers in each State capital city can provide additional

assistance for scheduled poisons (13 1126)

Skin Contact: Wash off immediately with soap and plenty of water removing all contaminated clothes and

shoes. Get medical attention if irritation develops. Consult a physician if necessary.

Eye Contact: Flush eye with water for 15 minutes. Get medical attention.

**Inhalation:** Move to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen.

Get medical attention.

**Ingestion:** Do not induce vomiting without medical advice. Never give anything by mouth to an

unconscious person. Obtain medical attention.

Most important symptoms and effects, both acute and delayed

Symptoms Causes eye irritation. May cause irritation of respiratory tract. May cause skin irritation and/or

dermatitis.

Indication of any immediate medical attention and special treatment needed

Notes to Physician: Treat symptomatically

**Protection of first-aiders** 

First-Aid Providers: Avoid exposure to blood or body fluids. Wear gloves and other necessary protective clothing. Dispose of contaminated clothing and equipment as bio-hazardous waste

#### 5. FIRE-FIGHTING MEASURES

**Extinguishing Media** 

Suitable Extinguishing Media: Use water spray, alcohol-resistant foam, dry chemical or

carbon dioxide.

Unsuitable Extinguishing Media: No information available.

Specific hazards arising from the chemical

Hazardous Combustion Products: Carbon monoxide. Carbon dioxide

Specific hazards: Slightly Flammable

When heated to decompositon it emits acrid smoke and

irritating fumes

**Special Protective Actions for Firefighters** 

**Specific Methods:** Water mist may be used to cool closed containers.

**Special Protective Equipment for Firefighters:** As in any fire, wear self-contained breathing apparatus

pressure-demand, MSHA/NIOSH (approved or equivalent)

and full protective gear

Product code: D1097 Product name: DIETHYL PHTHALATE. 3 / 13

#### 6. ACCIDENTAL RELEASE MEASURES

#### Personal precautions, protective equipment and emergency procedures

Personal Precautions: Use personal protective equipment. Ensure adequate ventilation. Avoid contact with skin, eyes

and clothing. Remove all sources of ignition. Avoid dust formation. Keep people away from and

upwind of spill/leak. All equipment used when handling the product must be grounded.

**Environmental precautions** Prevent product from entering drains. Prevent entry into waterways, sewers,

basements or confined areas.

#### Methods and material for containment and cleaning up

Methods for containment Prevent further leakage or spillage if safe to do so. Absorb spill with inert material

(e.g. vermiculite, dry sand or earth), then place in a suitable chemical waste

container.

**Methods for cleaning up**Use appropriate tools to put the spilled material in a suitable chemical waste disposal

container. Clean contaminated surface thoroughly.

#### 7. HANDLING AND STORAGE

#### Precautions for safe handling

#### **Technical Measures/Precautions:**

Provide sufficient air exchange and/or exhaust in work rooms. Avoid dust formation. Keep away from incompatible materials. All equipment used when handling the product must be grounded. Remove all sources of ignition.

#### Safe Handling Advice:

Wear personal protective equipment. Use only in well-ventilated areas. Keep container tightly sealed. Avoid contact with skin, eyes and clothing. Keep away from heat and sources of ignition. Do not breathe vapors or spray mist. Do not ingest. When using do not smoke. Handle in accordance with good industrial hygiene and safety practice.

#### Conditions for safe storage, including any incompatibilities

#### **Technical Measures/Storage Conditions:**

Keep containers tightly closed in a dry, cool and well-ventilated place. Store at room temperature in the original container. Keep away from heat and sources of ignition. Store in a segrated and approved area. Store away from incompatible materials.

#### **Incompatible Materials:**

Oxidizing agents. Acids. permanganates.

#### 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### **Control parameters**

#### **National occupational exposure limits**

#### **United States**

Sintod Statos							
Components	OSHA	NIOSH	ACGIH	AIHA WHEEL			
	None	= 5 mg/m <sup>3</sup> TWA	= 5 mg/m³ TWA	None			
Diethyl Phthalate - 84-66-2							

#### Canada

Components	Alberta	British Columbia	Ontario	Quebec
	= 5 mg/m <sup>3</sup> TWA	= 5 mg/m <sup>3</sup> TWA	5 mg/m <sup>3</sup> TWA	5 mg/m <sup>3</sup> TWAEV
Diethyl Phthalate - 84-66-2				

#### **Australia and Mexico**

Product code: D1097 Product name: DIETHYL PHTHALATE. 4 / 13

Components	Australia	Mexico
Diethyl Phthalate	None	= 5 mg/m <sup>3</sup> TWA
84-66-2		

#### Appropriate engineering controls

Engineering measures to reduce exposure: Ensure adequate ventilation. Provide exhaust ventilation or

other engineering controls to keep the airborne

concentrations of vapors and mist below their respective

threshold limit value.

#### Individual protection measures, such as personal protective equipment

**Personal Protective Equipment** 

Product code: D1097

**Eye protection:** Goggles.

**Skin and body protection:** Chemical resistant apron. Gloves.

**Respiratory protection:** Vapor respirator. Be sure to use an approved/certified respirator or equivalent.

**Hygiene measures:** Avoid contact with skin, eyes and clothing. When using, do not eat, drink or smoke.

Wash hands before breaks and immediately after handling the product.

#### 9. PHYSICAL AND CHEMICAL PROPERTIES

Product name: DIETHYL PHTHALATE, 5 / 13

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state: Appearance: Color:

Liquid Oily. Colorless to pale yellow.

Odor: Taste Molecular/Formula weight:

Odorless. Bitter. 222.24 g/mol

Formula: Flash point ( $^{\circ}$ C): Flashpoint ( $^{\circ}$ C/ $^{\circ}$ F):

C12H14O4 161°C 161°C/ 322°F

Flash Point Tested according to: Lower Explosion Limit (%): Upper Explosion Limit (%): O.7%(V) at 186°C(368°F) No information available

Autoignition Temperature (°C/°F): pH: Melting point/range(°C/°F):

457.0/ 854.6°F No information available -40.5°C/ 104.9°F

Boiling point/range(°C/°F): Decomposition temperature(°C/°F): Bulk density:

295°C/ 563°F No information available No information available

Specific gravity: Vapor pressure @ 20°C (kPa): Density (g/cm3):

No information available .0021mmHg 1.118-1.122

**Evaporation rate:** Vapor density: VOC content (g/L): No information available 7.7 No information available

Odor threshold (ppm): Partition coefficient Viscosity:

No information available (n-octanol/water): 11.53 mm^2/s @ 20°C

2.47

Miscibility: Solubility:

Miscible with vegetable oils, ketones, soluble in diethyl ether esters, aromatic hydrocarbons Soluble in Acetone

Soluble in Alcohol
Soluble in Benzene

Insoluble or very slightly soluble in cold

water

Solubility in water: 1280 mg/l @ 25°C

#### 10. STABILITY AND REACTIVITY

Reactivity

Reactive with acids

Reactive with oxidizing agents

**Chemical stability** 

Stability: Stable under recommended storage conditions

<u>Possibility of Hazardous Reactions:</u> May attack some forms of plastic. Incompatible with permanganates, nitric acid

**Conditions to avoid:** Heat. Ignition sources. Incompatible materials.

**Incompatible Materials:** Oxidizing agents. Acids. permanganates.

Hazardous decomposition products: Carbon monoxide. Carbon dioxide.

**Other Information** 

**Corrosivity:** No information available

Special Remarks on Corrosivity: No information available

Product code: D1097 Product name: DIETHYL PHTHALATE, 6 / 13

#### 11. TOXICOLOGICAL INFORMATION

#### Information on likely routes of exposure

#### **Principal Routes of Exposure:**

Eyes. Skin. Inhalation. Ingestion.

#### **Acute Toxicity**

#### **Component Information**

Diethyl Phthalate - 84-66-2

**LD50/oral/rat** = 8600-9500 mg/kg Oral LD50 Rat

**LD50/oral/mouse** = 6172 mg/kg Oral LD50 Mouse (LOLI) (RTECS)

6172-8600mg/kg (EU comission) (IUCLID Dataset)

LD50/dermal/rat = >11200 mg/kg Dermal LD50 Rat

>22400 mg/kg Dermal LD50 Rat

LD50/dermal/rabbit = 22400 mg/kg Dermal LD50 Rabbit

LC50/inhalation/rat = No information available

LC50/inhalation/mouse = 4.89 mg/l

Other LD50 or LC50information = 1000-4000mg/kg Oral LD50 Rabbit

5000-8600 mg/kg Oral LD50 Guinea Pig >20 ml/kg Dermal LD50 Guinea Pig

4.64 mg/l Inhalation LC50 Rat 6/H

#### **Product Information**

LD50/oral/rat =

VALUE- Acute Tox Oral = 8600mg/kg

LD50/oral/mouse =

Value - Acute Tox Oral = 6172mg/kg

LD50/dermal/rabbit

VALUE-Acute Tox Dermal = > 22400mg/kg

LD50/dermal/rat

VALUE -Acute Tox Dermal = 11200mg/kg

LC50/inhalation/rat

VALUE-Vapor = No information available

**VALUE-Gas =** No information available

VALUE-Dust/Mist = No information available

LC50/Inhalation/mouse

VALUE-Vapor = 4.89 mg/l

VALUE - Gas = No information available

VALUE - Dust/Mist = No information available

**Symptoms** 

**Skin Contact:** May cause skin irritation. May be absorbed through the skin. Prolonged skin contact

causes dermatitis.

**Eye Contact:** Causes eye irritation. Causes lacrimation.

Product code: D1097 Product name: DIETHYL PHTHALATE, 7 / 13

**Inhalation** Breathing in mist or vapor may cause respiratory tract (nose, throat) irritation.

Symptoms inlcude coughing and hoarseness, and dyspnea. Contact with mist or vapor may cause lacrimation. Inhalation of high concentrations may affect behavior/central nervous system (central nervous system depression, headache, dizziness, polyneuropathy (paresthesia), and pain, numbness, weakness, muscle

spasms in the arms and legs.

. Sensitive individuals may develop allergic reaction similar to asthma when

chronically exposed to diethyl phthalate.

**Ingestion** Ingestion of large doses may cause gastrointestinal tract irritation. May affect

behavior/central nervous system (somnolence, withdrawl and other symptoms similar to that of inhalation), metabolism (weight loss). Prolonged or repeated ingestio may affect the liver, metabolism (weight loss), blood (changes in serum composition), urinary system (bladder), behavior/central nervous system. May cause pupilliary

constriction...

Aspiration hazard No information available

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Chronic Toxicity No information available

Sensitization: No information available

Mutagenic Effects: Experiments with bacteria and/or yeast have shown mutagenic effects

Mutations in microorganisms

Carcinogenic effects: Not considered carcinogenic

Components	ACGIH - Carcinogens	IARC	NTP	OSHA HCS - Carcinogens	Australia - Prohibited Carcinogenic Substances	Australia - Notifiable Carcinogenic Substances
Diethyl Phthalate	A4 Not Classifiable as a Human Carcinogen	Not listed	Not listed	Not listed	Not listed	Not listed

Reproductive toxicity No data is available

Reproductive Effects: May cause adverse reproductive effects based on animal data. It has not been

shown to affect reproduction in humans.

**Developmental Effects:** May cause adverse developmental effects based on animal data

No information on developmental toxicity effects on humans was found

**Teratogenic Effects:** Teratogenicity was found only in animal studies when given in large doses to

produce maternal toxicity. Not found teratogenic at lower doses. No human data

available.

**Specific Target Organ Toxicity** 

STOT - single exposure
STOT - repeated exposure
No information available
No information available

Target Organs: Liver. Central nervous system.

#### 12. ECOLOGICAL INFORMATION

#### **Ecotoxicity**

Product code: D1097 Product name: DIETHYL PHTHALATE, 8 / 13

#### 12. ECOLOGICAL INFORMATION

**Ecotoxicity effects:** Harmful to aquatic organisms.

Diethyl Phthalate - 84-66-2

Freshwater Algae Data: 2.11 - 4.29 mg/L EC50 Pseudokirchneriella subcapitata 96 h

42 - 255 mg/L EC50 Pseudokirchneriella subcapitata 72 h

21 mg/L EC50 Desmodesmus subspicatus 96 h 23 mg/L EC50 Desmodesmus subspicatus 72 h

16.8 mg/L LC50 Pimephales promelas 96 h static 1 Freshwater Fish Species Data:

22 mg/L LC50 Lepomis macrochirus 96 h flow-through 1 17 mg/L LC50 Pimephales promelas 96 h flow-through 1 12 mg/L LC50 Oncorhynchus mykiss 96 h flow-through 1 16.7 mg/L LC50 Lepomis macrochirus 96 h static 1

Water Flea Data: 36 - 74 mg/L EC50 Daphnia magna 48 h

86 mg/L EC50 Daphnia magna 48 h

Persistence and degradability: Biodegradable (94.6 % after 28 days)

An estimated Biocentration Factor (BCF) value of 117. Bioaccumulative potential:

Mobility: No information available

#### 13. DISPOSAL CONSIDERATIONS

#### **Disposal Methods**

#### Waste from residues / unused products:

Waste must be disposed of in accordance with Federal, State and Local regulation.

#### Contaminated packaging:

Empty containers should be taken for local recycling, recovery or waste disposal

Components	RCRA - F Series Wastes	RCRA - K Series Wastes	RCRA - P Series Wastes	RCRA - U Series Wastes
Diethyl Phthalate	None	None	None	U088

#### 14. TRANSPORT INFORMATION

DOT

UN-No: Not Regulated

**Proper Shipping Name:** No information available **Hazard Class:** No information available No information available **Subsidiary Risk:** 

**Packing Group:** None

**ERG No:** No information available

**Marine Pollutant** No data available

DOT RQ (lbs): No information available

TDG (Canada)

UN-No: Not Regulated

**Proper Shipping Name:** No information available **Hazard Class:** No information available

Product code: D1097 9 / 13 Product name: DIETHYL PHTHALATE,

#### 14. TRANSPORT INFORMATION

Subsidiary Risk:No information availablePacking Group:No information availableDescription:No information available

**ADR** 

**UN-No:** Not Regulated

Proper Shipping Name:
Hazard Class:
Packing Group:
Subsidiary Risk:
Classification Code:
Description:
No information available

**IMO / IMDG** 

UN-No: Not Regulated

No information available **Proper Shipping Name: Hazard Class:** No information available **Subsidiary Risk:** No information available Packing Group: No information available **Description:** No information available **IMDG Page:** No information available **Marine Pollutant** No information available MFAG: No information available **Maximum Quantity:** No information available

**RID** 

**UN-No:** Not Regulated

Proper Shipping Name:
Hazard Class:
Subsidiary Risk:
Packing Group:
Classification Code:
Description:
No information available

**ICAO** 

**UN-No:** Not Regulated

Proper Shipping Name:
Hazard Class:
Subsidiary Risk:
Packing Group:
No information available

**IATA** 

UN-No: Not Regulated

Proper Shipping Name:
Hazard Class:
Subsidiary Risk:
Packing Group:
No information available

#### 15. REGULATORY INFORMATION

International Inventories

Product code: D1097 Product name: DIETHYL PHTHALATE, 10 / 13

Components	U.S. TSCA	KOREA KECL	Philippines (PICCS)	Japan ENCS	CHINA	Australia (AICS)	EINECS-No.
Diethyl Phthalate	Present	Present KE- 02216	Present	Present (3)- 1301	Present	Present	Present 201-550-6

#### **U.S. Regulations**

Diethyl Phthalate

Massachusetts RTK: Present

New Jersey RTK Hazardous Substance List: 0707

New Jersey (EHS) List: 0707 500 lb TPQ

New Jersey - Discharge Prevention - List of Hazardous Substances: Present

Pennsylvania RTK: Environmental hazard

Pennsylvania RTK - Environmental Hazard List Present

Pennsylvania RTK - Special Hazardous Substances Present

Minnesota - Hazardous Substance List: Present

New York Release Reporting - List of Hazardous Substances:

= 1 lb RQ

= 1000 lb RQ

Louisana Reportable Quantity List for Pollutants: Listed California Directors List of Hazardous Substances: Present

#### California Prop. 65: Safe Drinking Water and Toxic Enforcement Act of 1986.

#### Chemicals Known to the State of California to Cause Cancer:

This product does not contain a chemical requiring a warning under California Prop. 65. (See table below)

#### Chemicals Known to the State of California to Cause Reproductive Toxicity:

This product does not contain a chemical requiring a warning under California Prop. 65. (See table below)

Components	Carcinogen	Developmental Toxicity	Male Reproductive	Female Reproductive
			Toxicity	Toxicity:
Diethyl Phthalate	Not Listed	Not Listed	Not Listed	Not Listed

#### **CERCLA/SARA**

•	CERCLA - Hazardous Substances and their Reportable Quantities	Hazardous	Hazardous	<b>Chemical Category</b>	Section 313 - Reporting de minimis
	= 1000 lb final RQ = 454 kg final RQ	None	None	None	None

#### U.S. TSCA

•	TSCA Section 5(a)2 - Chemicals With Significant New Use Rules (SNURS)	TSCA 8(d) -Health and Safety Reporting
Diethyl Phthalate	Not Applicable	Not Applicable

#### Canada

#### WHMIS hazard class:

Non-controlled

#### **Diethyl Phthalate**

Uncontrolled product according to WHMIS classification criteria

#### **Canada Controlled Products Regulation:**

This product has been classified according to the hazard criteria of the CPR (Controlled Products Regulation) and the MSDS contains all of the information required by the CPR.

Components	WHMIS Ingredient Disclosure List -
Diethyl Phthalate	0.1 %

Product code: D1097 Product name: DIETHYL PHTHALATE, 11 / 13

#### Inventory

Components		Canada (NDSL)
Diethyl Phthalate	Present	Not Listed

Components	CEPA Schedule I - Toxic Substances	CEPA - 2010 Greenhouse Gases Subject to Manditory Reporting
Diethyl Phthalate	Not listed	Not listed

#### **EU Classification**

R-phrase(s) not determined (not applicable)

#### S -phrase(s)

none

Components	Classification	Concentration Limits:	Safety Phrases
Diethyl Phthalate		No information	

The product is classified in accordance with Annex VI to Directive 67/548/EEC

#### Indication of danger:

Xn - Harmful.

### **16. OTHER INFORMATION**

Product code: D1097

Product name: DIETHYL PHTHALATE, 12 / 13



#### Manufacturer

Product Covered: D1097, Diethyl Phthalate, NF

Spectrum takes ownership as the manufacturer for the Spectrum product listed above and provides full quality assurance, customer service, and technical product support.

While information concerning the raw material manufacturer of our starting materials is considered proprietary, such information can be made available upon request contingent on demonstration of business volume justification and successful execution of confidential disclosure agreement (CDA).

Requests for disclosure of proprietary raw material manufacturer information may be submitted to the assigned account representative for consideration.

Sincerely,

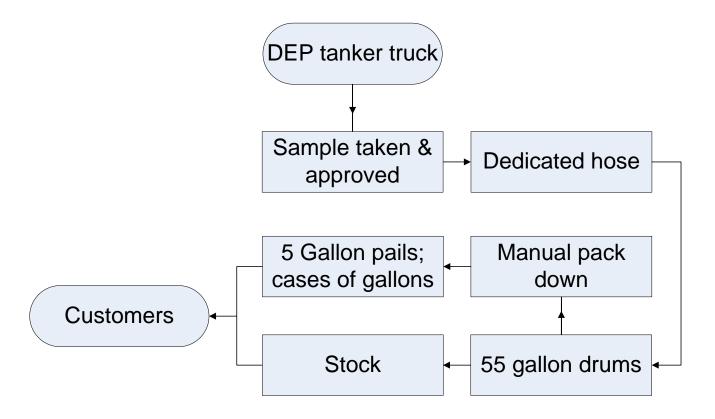
Alan Wang, MSQA, ASQ CQA Director of Technical Services

techservices@spectrumchemical.com



## **Manufacturing Process Flowchart**

## Diethyl Phthalate, NF - D1097



### Spectrum Chemical Mfg Corp

# **Certificate of Registration**



This is to certify that the quality management system of

## Spectrum Chemicals and Laboratory Products, Lac

Main Site: 14422 South San Pedro Street, Gardena, California, 90248, USA

Additional Sites: 13915 South Main Street, Los Angeles, California, 90061, USA 755 Jersey Avenue, New Brunswick, New Jersey, 08901, USA 769 Jersey Avenue, New Brunswick, New Jersey, 08901, USA 7400 North Oracle Road, Suite 221, Tucson, Arizona, 85704, USA

has been assessed and registered by Intertek as conforming to the requirements of

ISO 9001:2008

The quality management system is applicable to

**California and New Jersey sites:** The manufacture and distribution of specialty fine chemicals, solutions, equipment, supplies and products for the laboratory, pharmaceutical, food, healthcare, cosmetic, fragrance, biotechnology, environmental and process industries.

**Arizona site:** Supporting Spectrum's two manufacturing facilitates by: selecting and qualifying distributors of Laboratory and Safety Equipment; processing bids and quotes to generate new sales opportunities; sourcing bulk chemicals in support of bulk bids and quotes; assisting production operations through order expediting and IT infrastructure support.

Certificate Number: 94-316m-01

Initial Certification Date: 27 December 1994 Certificate Issue Date: 29 January 2016 Certificate Expiry Date: 14 September 2018

Calin Moldovean, President Intertek Testing Services NA, Inc. 900 Chelmsford Street, Suite 301-3, Lowell, MA, USA ARAB
ACCREDITED
ISO/IEC17021
MANAGEMENT SYSTEMS
CERTIFICATION BODY



In the issuance of this certificate, Intertek assumes no liability to any party other than to the Client, and then only in accordance with the agreed upon Certification Agreement. This certificate's validity is subject to the organization maintaining their system in accordance with Intertek's requirements for systems certification. Validity may be confirmed via email at <a href="mailto:certificate.validation@intertek.com">certificate.validation@intertek.com</a> or by scanning the code to the right with a smartphone.

# **Certificate of Registration**



This is to certify that the quality management system of

## Spectrum China Ltd.

Building A20, No. 3802, Shengang Road, Songjiang District, Shanghai, China

has been assessed and registered by Intertek as conforming to the requirements of

ISO 9001: 2008

The quality management system is applicable to:

Provision of service of purchase, testing and sales for chemical products, repacking of non-hazardous chemical products.

Organization Code: 77762704-8
Certificate Number: 111310001-01
Certificate Issue Date: 17 November 2015
Certificate Expiry Date: 14 September 2018







Authorised Signature: Calin Moldovean – President, Business Assurance Intertek Certification Limited, 10A Victory Park, Victory Road, Derby DE24 8ZF, United Kingdom Intertek Certification Limited is a UKAS accredited body under schedule of accreditation no. 014.

In the issuance of this certificate, Intertek assumes no liability to any party other than to the client, and then only in accordance with the agreed upon Certification Agreement. This certificate's validity is subject to the organization maintaining their system in accordance with Intertek's requirements for systems certification. Validity may be confirmed via email at <a href="mailto:certificate.com">certificate.com</a> or by scanning the code to the right with a smartphone.

The annual validity of the certificate can also be checked through the website <a href="http://www.cnca.gov.cn">http://www.cnca.gov.cn</a> of CNCA in China.





January 03, 2017

#### **Certificate of cGMP**

#### Dear Valued Customer:

Spectrum Chemicals and Laboratory Products certifies that our USP, NF, FCC, EP, BP, JP, and food grade products are produced, processed, packaged and held in compliance with current Good Manufacturing Practices (cGMP) in accordance with the applicable parts of 21 CFR, parts 210 and 211 of the Code of Federal Regulations.

Spectrum is an FDA registered and inspected drug establishment. Our United States Food and Drug Administration (USFDA) Registration numbers are as follow:

Spectrum Gardena, California: 2020632

Spectrum New Brunswick, New Jersey: 2246824

Thank you for your interest with Spectrum products. Please feel free to contact me at 310-516-8000, extension 5610 or via email at <a href="mailto:mdang@spectrumchemical.com">mdang@spectrumchemical.com</a> if I may be of further assistance.

Sincerely,

Michael Dang

Manager, GMP Compliance

CORPORATE HEADQUARTERS

769 Jersey Avenue New Brunswick, NJ 08901 PHONE 732.214.1300

FAX 732.246.7132

WEST COAST FACILITY

14422 South San Pedro Street Gardena, California 90248 PHONE 310.516.8000 FAX 310.516.9843



July 18, 2016

#### **Certificate of cGMP**

#### Dear Valued Customer:

Spectrum Chemicals and Laboratory Products certify that the following product(s) is produced, processed, packaged and held in compliance with current Good Manufacturing Practices (cGMP) in accordance with the applicable parts of 21 CFR, parts 210 and 211 of the Code of Federal Regulations.

Catalog Number	Product Name	
D1097	Diethyl Phthalate, NF	

Spectrum is an FDA registered and inspected drug establishment. Our United States Food and Drug Administration (USFDA) Registration numbers are as follows:

Spectrum-Gardena, CA: 2020632
Spectrum-New Brunswick, NJ: 2246824
Spectrum-Shanghai, China: 3006174778

Thank you for your interest with Spectrum products. Please feel free to contact the Quality Assurance department at 310-516-8000 or via email at <a href="mailto:qualityassurance@spectrumchemical.com">qualityassurance@spectrumchemical.com</a> if we may be of further assistance.

Sincerely,

Oralia Chavez

**Quality Assurance Specialist** 

Oulu Almy



April 28, 2016

Re: Diethyl Phthalate, NF- D1097

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

We at Spectrum Chemical Mfr. Corp. understand the concern regarding Bovine Spongiform Encephalopathy (BSE). Please be assured that the chemical

Diethyl Phthalate, NF- D1097

is BSE/TSE free.

If you have any further questions, please contact Tech Services at (310) 516-8000 Extension 5471, or by email at <a href="mailto:techservices@spectrumchemical.com">techservices@spectrumchemical.com</a>.

Sincerely,

Darlene Dagdag-Lyudmirskiy Technical Services Spectrum Chemical Mfr. Corp.

This document has been produced electronically and is valid without a signature



April 28, 2016

Re: Diethyl Phthalate, NF- D1097

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

We at Spectrum Chemical Mfr. Corp. understand the concern regarding the presence of allergens in raw materials. Please be assured that the following chemical does not contain (Milk; Egg; Fish; Shellfish; Sulfur dioxide and sulfites at concentrations of more than 10 mg/kg or 10 mg/liter expressed as SO<sub>2</sub>; Lupin; Tree nuts; Mollusks; Wheat; Peanuts; Soy; Cereals containing Gluten; Celery; Mustard; Sesame Seed).

Diethyl Phthalate, NF- D1097

If you have any further questions, please contact Tech Services at (310) 516-8000 Extension 5471, or by email at <a href="mailto:techservices@spectrumchemical.com">techservices@spectrumchemical.com</a>.

Sincerely,

Darlene Dagdag-Lyudmirskiy Technical Services Spectrum Chemical Mfr. Corp.

This document has been produced electronically and is valid without a signature



May 5, 2016

Re: Diethyl Phthalate, NF-D1097

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

We at Spectrum Chemical Mfg. Corp. understand the concern regarding Aflatoxins in raw materials. To the best of our knowledge, the product listed below is not contaminated with Aflatoxins. Aflatoxins are not used in production. The following product does not come in contact with Aflatoxins at any stage of production.

Diethyl Phthalate, NF-D1097

If you have any further questions, please contact Tech Services at (310) 516-8000 Extension 5471, or by email at <a href="mailto:techservices@spectrumchemical.com">techservices@spectrumchemical.com</a>.

Sincerely,

Darlene Dagdag-Lyudmirskiy Technical Services Spectrum Chemical Mfr. Corp.

This document has been produced electronically and is valid without a signature



## **Certificate Of Analysis**

Item Number	D1097	Lot Number	1EF0970
Item	Diethyl Phthalate, NF		
CAS Number	84-66-2		
Molecular Formula	$C_{I2}H_{I4}O_4$	Molecular Weight	222.24

Test	Specification		Result
	min	max	
ASSAY (ANHYDROUS BASIS)	98.0%	102.0 %	99.85 %
REFRACTIVE INDEX @ 20°C	1.500	1.505	1.502
SPECIFIC GRAVITY @ 20°C	1.118	1.122	1.120
ACIDITY		TO PASS TEST	PASSES TEST
WATER		0.2 %	0.18 %
RESIDUE ON IGNITION		0.02 %	<0.02 %
IDENTIFICATION		TO PASS TEST	PASSES TEST
EXPIRATION DATE			26-FEB-2020
RESIDUAL SOLVENTS		TO PASS TEST	NO RESIDUAL SOLVENTS USED
APPEARANCE			CLEAR COLORLESS LIQUID
MANUFACTURE DATE			26-FEB-2015

Spectrum Chemical Mfg Corp 14422 South San Pedro Street Gardena 90248 CA



Certificate of Analysis Results Certified By:

Adan Hernandez

Quality Control Manager

Spectrum Chemicals & Laboratory Products

All pharmaceutical ingredients are tested using current edition of applicable pharmacopeia.

Read and understand label and MSDS/SDS before handling any chemicals. All Spectrum's chemicals are for manufacturing, processing, repacking or research purposes by experienced personal only. The customer must ensure to provide its users adequate hazardous material training and appropriate protective gears before handling our chemicals.



## **Certificate Of Analysis**

Item Number	D1097	Lot Number	2EF0519
Item	Diethyl Phthalate, NF		
CAS Number	84-66-2		
Molecular Formula	$C_{I2}H_{I4}O_4$	Molecular Weight	222.24

Test	Specification		Result
	min	max	
ASSAY (ANHYDROUS BASIS)	98.0%	102.0 %	99.85 %
REFRACTIVE INDEX @ 20°C	1.500	1.505	1.502
SPECIFIC GRAVITY @ 20°C	1.118	1.122	1.120
ACIDITY		TO PASS TEST	PASSES TEST
WATER		0.2 %	0.18 %
RESIDUE ON IGNITION		0.02 %	<0.02 %
IDENTIFICATION		TO PASS TEST	PASSES TEST
EXPIRATION DATE			26-FEB-2020
RESIDUAL SOLVENTS		TO PASS TEST	NO RESIDUAL SOLVENTS USED
APPEARANCE			COLORLESS LIQUID
DATE OF MANUFACTURE			26-FEB-2015

Spectrum Chemical Mfg Corp 755 Jersey Avenue New Brunswick 08901 NJ



Certificate Of Analysis Results Certified by

lbad Tirmizi Director of Quality

Spectrum Chemical Mfg. Corp.

All pharmaceutical ingredients are tested using current edition of applicable pharmacopeia.

Read and understand label and MSDS/SDS before handling any chemicals. All Spectrum's chemicals are for manufacturing, processing, repacking or research purposes by experienced personal only. The customer must ensure to provide its users adequate hazardous material training and appropriate protective gears before handling our chemicals.



### **Label Information**

The Spectrum label presents technical and safety information in an easily understood format. Our technical specialists stay abreast of the latest requirements of the Globally Harmonized System for Classification and Labelling of Chemicals (GHS), as well as the Occupational Safety and Health Administration (OSHA), the Food and Drug Administration (FDA) and other government regulatory agencies in order to ensure compliance, accuracy and concise hazard communication.



- A Bar Code
- GHS Hazard Pictograms
- Warning, Safety Data and Precautionary Information
- Product Catalog Number
- Item Name, Form, Grade
- Storage Color Band

- Size/Quantity
- Chemical Abstracts Service (CAS) Registry Number
- Caution Information
- DOT Shipping Information
- Toll-Free 24-Hour Chemical Emergency Telephone Number
- Empirical Formula, Formula Weight and Technical Specifications Panel
- Expiration Information
- Lot Number
- Kosher Certified by Kosher Supervision of America (KSA).

This color-coded band indicates the hazard most likely to be posed by that material under storage conditions. The criteria used to assign band colors have been established by the Storage Code working group of the Society for Chemical Hazard Communication (SCHC). It is recommended that like colors be stored together, unless otherwise stated, based on the color codes indicated to the right. However, it is the responsibility of the customer to check with their local fire department for possible conflicts with our recommendations when storing hazardous chemicals.

## YELLOW: Oxidizer **RED**: Flammable **GREEN**: General Storage **BLUE**: Health Hazard

WHITE: Corrosive

#### Spectrum Chemical Mfg Corp

Corporate Headquarters:

769 Jersey Ave.

New Brunswick, NJ 08901

732.214.1300

West Coast Facility:

14422 S. San Pedro St.

Gardena, CA 90248

310.516.8000



January 26, 2016

#### RE: Lot Numbering System

Dear Valued Customer:

This letter is to inform you of Spectrum Chemicals and Laboratory Products' Lot Numbering System. The system is based on an alpha-numerical sequence which provides the month, year and location of production.

The lot numbering system utilized until 2010 is a sequence of **six characters**, two letters followed by four numbers. The first letter represents the year, for example, Y denotes 2009 and Z denotes 2010. The second letter represents the month and site, for example, A-L denotes January through December at Spectrum's Gardena, CA facility, while M-X denotes January through December at the New Brunswick, NJ facility. The following four numbers are sequentially assigned.

**Example**: Zl0928 = The 928<sup>th</sup> material produced in California in September 2010

The lot numbering system utilized for 2011 and forward, is a sequence of **seven characters**. The first character, a number, represents the production facility:

1 = Gardena, CA Facility

2 = New Brunswick, NJ Facility

3 = China Facility

The second character, a letter, represents the year. For example, A denotes 2011 and B denotes 2012. The third character, a letter, represents the month, with A denoting January and L denoting December. The following four numbers are sequentially assigned.

**Example**: 2AA0706 = The 706<sup>th</sup> material produced in New Jersey in January 2011

Thank you for your interest with Spectrum products. Please feel free to contact us at 310-516-8000 or via email at <a href="mailto:qualityassurance@spectrumchemical.com">qualityassurance@spectrumchemical.com</a> if we may be of further assistance.

Sincerely,

Michael Dang

Manager, GMP Compliance



### **Stability – Shelf Life Guidance**

Product Covered: D1097, Diethyl Phthalate, NF

Spectrum Chemical's manufacturing partner has assigned the following shelf life guidance for the product listed above.

The product, D1097, Diethyl Phthalate, NF, is assigned a 60 months shelf life from date of manufacturing. The quality and integrity of the chemical depends on the handling and storage conditions. Please refer to the Safety Data Sheet for proper storage and handling procedures.

Adan R. Hernandez Quality Control Manager

Corporate Headquarters 769 Jersey Avenue New Brunswick, NJ 08901-3605